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K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER BARHAM, BETHANY P	
			ART UNIT 1615	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/510,126	<b>Applicant(s)</b> PEREZ-CAMARGO ET AL.	
	<b>Examiner</b> BETHANY BARHAM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 November 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-49, 52, 53, 55 and 58-71 is/are pending in the application.
- 4a) Of the above claim(s) 38-47 and 61-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 49, 52, 53, 55 and 58-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

Receipt of Applicant's Response and claim amendments filed on 6/15/09 and 5/21/09 are acknowledged. Claims 38-49, 52-53, 55 and 58-71 are pending. Claims 38-47 and 61-71 remain withdrawn. Claims 48-49, 52-53, 55 and 58-60 are rejected.

## **MAINTAINED REJECTIONS**

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 58, which depends from claim 55 relating to whey protein and protease, states "wherein the fat transportation agent has a fatty acid profile specially-selected to improve absorption", while claim 59 states "wherein the fatty acid profile is polyunsaturated". The whey protein and protease do not have 'polyunsaturated' or a 'fatty acid profile' nor does the instant spec teach that they improve absorption, but rather that they 'help the formation of lipoproteins' (instant

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spec pg. 10, lines 14-15). The instant specification does teach that fish oil, prebiotic, probiotics, etc improve absorption and that polyunsaturates such as fish oils enhance absorption (pg. 10, lines 21-27), but nowhere are whey protein and/or protease taught to have this function of improving absorption or being polyunsaturates of fish oil. This is a new matter rejection.

**NEW:**

Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 48 claims ranges of “about 3 to about 12%” of an omega-3 fatty acid and “about 6 to 16% of an anti-inflammatory agent”. Nowhere in the instant specification is the range “about 3 to about 12%” disclosed, “3% to 12% of an omega-3 oil” is taught at pg. 10, lines 34, and generally intestinal mucosa function promoters may be present from “about 6% to 16%” but it is not specifically related to anti-inflammatory agents alone. This is a new matter rejection.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 48 recites the broad recitation of "about 6 to 16% of an anti-inflammatory agent", and the claim also recites "about 3 to about 12% of an omega-3 fatty acid" which is the narrower statement of the range/limitation. The instant specification teaches that anti-inflammatory agents are omega-3 fatty acids (pg. 7, lines 7-8), and not lactoferrin, prebiotic, probiotic (pg. 7, lines 5-6), thus the amendment to include an "anti-inflammatory agent" is confusing, repetitive and indefinite when the claim already claims omega-3 fatty acids. The instant

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specification does not cite any other "anti-inflammatory agent" other than the already claimed omega-3 fatty acids.

Further confusing is the portion cited by Applicant for support of the "anti-inflammatory agent" (pg. 10, lines 21-27) which appears only to be a generic teaching of intestinal mucosa function promoters, which may be present from "about 6% to 16%" and not specifically related to anti-inflammatory agents alone. Please clarify. For the purposes of examination a composition containing an amount of "3% to 12%" or "about 6 to 16%" of fish oil will meet the instant claimed composition of an intestinal mucosa function promoter and an anti-inflammatory agent since both are taught by the instant spec to be omega-3 fatty acids of fish oil.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48-49, 52-53 and 58-59 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,759,933 ('933).

The instant claims are drawn to a nutrition management regimen comprising a dietary component for feeding regularly, according to predetermined directions, to a pet animal, the dietary component comprising a first pancreatic function promoter, a second pancreatic function promoter, and an intestinal mucosa function-promoter in an amount effective to maintain, promote or enhance the capacity of the pet to digest lipid, wherein

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the intestinal mucosa function-promoter comprises about 3% to about 12% of an omega-3 fatty acid derived from fish oils and about 6% to 16% of an anti-inflammatory agent, the first pancreatic function promoter is a pancreatic extract, and the second pancreatic function promoter is a gut pH modifier selected from the group consisting of a prebiotic, a probiotic and combinations thereof.

- '933 teaches a product comprising fish meat mixed with an oil and further consisting of proteolytic enzymes and/or protein digesting micro-organisms (abstract, claims 10, 13 and 16). '933 teaches mixtures of pancreatin (a proteolytic enzyme) and lactobacilli (a protein digesting micro-organisms, or instant spec teaches this is a probiotic pg. 12) and fats/oils such as fish oil (col. 2, lines 45, col. 3, lines 1 and 10-30; Examples 26 and 29; note according to the instant specification anti-inflammatory agents include fish oils containing omega-3 fatty acids (pg. 7, lines 7-8 and pg. 10, lines 21-27). According to '933 the fat/oil component is included in an amount from 5-40% (col. 5, lines 9-10) (meeting the limitations of claim 48).
- '933 teaches adding egg or soybean (instant spec teaches these are emulsifiers and therefore liver function promoters pg. 13) (col. 2, lines 28 and 40-42) (meeting the limitations of claims 49 and 52-53).
- '933 teaches papain (col. 2, line 67) (a protease according to the instant spec pg. 10) (meeting the limitations of claim 55 and 58-59).

***Claim Rejections - 35 USC § 103***

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 48-49, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119237 ('237) in view of US 4,759,933 ('933).

- '237 teaches a probiotic food supplement directed to veterinary applications comprising 1-5% fish oil, antioxidants and probiotic ingredients comprising one or more probiotic microorganisms and enzymes (abstract, claims 7, and 13). Examples 2 and 3 teach cod liver oil (a fish oil) in amounts of 0.001-60% by weight, enzyme (papaya extract) and probiotic bacteria and oligosaccharides (meeting the limitations of claim 48).
- '237 teaches compositions with vitamins such as tocopherol (instant spec teaches that this is a glutathione promoter pg. 13), taurine (liver function promoter), etc (Examples 1-3) (meeting the limitations of claims 49, 52-53).
- '237 does not teach the specific enzyme pancreatic lipase instant claimed.
- '933 teaches enzymes useful in food products include extracts from papaya (papain) or pancreas (pancreatin) (col. 2, line 63-col. 3, line 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '237 in view of '933. A skilled artisan would know how to substitute one enzyme papain of '237 for the specific enzyme pancreatin of '933 with



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predictable results because each is taught as useful in food products. Such a substitution of one enzyme for another is within the purview of the skilled artisan.

Claims 48-49, 52-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,210,718 ('718).

- '718 teaches a nutrient composition comprising proteins, fats such as fish oil in an amount no more than 5% (col. 7, lines 35-42), palatability modifiers such as fish oil in amounts of 0.0001-10% (col. 9, lines 41-53), an enzyme such as lipase as a digestion aid (col. 8, lines 19-26), probiotics to benefit the gastrointestinal flora such as lactobacillis, etc (col. 8, lines 38-62) (meeting the limitations of claim 48).
- '718 teaches that the enzymes, microorganisms, etc promote enhance digestive activity, nutrient absorption or maturation of the gastrointestinal system as a whole (col. 11, lines 55-62).
- '718 teaches adding vitamins and minerals such as vitamin E (instant spec teaches that this is a glutathione promoter pg. 13) (col. 8, lines 28-38) (meeting the limitations of claims 49, and 52-53).
- '718 teaches that the proteins can be from whey (col. 7, line 24) (meeting the limitations of claims 55 and 58-60).
- '718 does not teach a single embodiment with all these components, but does teach that the components form a nutrient formulation for poultry and animals. A reference is analyzed using its broadest teachings. MPEP 2123 [R-5].

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“[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 “need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.” KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that “[a] person of ordinary skill is... a person of ordinary creativity, not an automaton.” Id. at 1742.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to rearrange the known components of ‘718 into a single formulation and obtain a nutrient composition for animals as disclosed by ‘718 that benefit the gastrointestinal flora, aids in digestion, etc to yield predictable results. Such a rearrangement is within the purview of the skilled artisan who is not an automaton.

Claims 48-49, 52-53, 55 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,471,999 ('999) in view of EP 1 048 226 ('226) or US 6,576,667 ('667).

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- '999 teach a pet milk powder as nutritional milk that results in reduced gastrointestinal intolerance (abstract). '999 teaches that the milk powder when administered in an effective amount with the nutritional composition reduces gastrointestinal intolerance and that it may further comprise one or more lipid source, protein source, vitamins and minerals, and teaches a specific aspect which comprises lactose (of micro-organism origin), lactase (an enzyme), taurine, arginine and choline (claims 1-9; col. 2, lines 9-lines 26).
- '999 teaches omega fatty acids such as soybean and rapeseed oil and in Examples 1-2 (col. 3, lines 15-20).
- '999 teaches chicory fibers, inulin, fructooligosaccharides with the probiotic micro-organism have a symbiotic relationship for promoting beneficial effects (col. 4, lines 9-14) (according to the limitations of claim 48).
- '999 teaches including an alkali in the milk-based powder, which slows the pH drop in the gastrointestinal tract (col. 2, lines 53-55). '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (meets the limitations of claims 49, 52-53 and 55, 58-60 since whey protein, omega-3 and taurine are all taught).
- '999 teaches that the amount of nutritional composition is to be fed to a mammal each day depends of factors such as age, type of mammal (dogs and cats), and other nutritional sources (col. 4, lines 25-36).

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- Examples 1 and 2 teach mixing the milk powder, galactosidase (lactase amino, an enzyme), vitamins, minerals, and soybean oil, and adding water to provide nutritional supplement to dogs and puppies or cats.
- '999 teaches that a protein source of whey protein and further supplemented with taurine and a probiotic micro-organism which beneficially effects the host by improving its intestinal microbial balance, such as lactic acid (col. 3, lines 25-40) (according to the limitations of claims 55 and 58-60).
- '999 does not teach omega fatty acids derived from fish oil, a % of fish oil or the specific enzyme lipase, but does teach an oil component and an enzyme.
- Example 1 of '226 teaches a formulation comprising whey protein concentrate, pancreatin (a known pancreatic extract or lipase), fish oil (5.2 g), soya oil, vitamins/minerals and various amino acids including glutamic acid, cystine and glycine (which are glutathione promoters). '226 has a lipid source such as fish oil in an amount of about 15-35% with the ratio of n-6 to n-3 fatty acids of 5:1 to about 15:1 (pg. 3, lines 39-47), which overlaps with the instant claimed omega-3 fatty acid range.
- '667 Example 7 teaches a composition comprising lipase and an emulsifier mixed with fish oil present in an amount of 10% by weight.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine '999 in view of '226 or '667. A skilled artisan would know how to substitute a known omega-3-fatty acid of rapeseed oil and a known enzyme of '999 for the specific the fish oil and lipase of '226 or '667 into the pet food composition of '999. It

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is within the purview of the skilled artisan to substitute one known omega fatty acid and one known enzyme for another with predictable results.

### ***Response to Arguments***

Applicant's arguments with respect to claims 48-49, 52-53, 55 and 58-60 have been considered but are not persuasive and moot in view of the new grounds of rejection necessitated by applicants' amendments. Applicant argues that the instant spec has support for the instant claimed "fat transportation agent has a fatty acid profile specially-selected to improve absorption" and "wherein the fatty acid profile is polyunsaturated" of instant claims 58-59 and that the claims depend from claim 55, which depends from claim 48. The Examiner respectfully points out that while the specification does indeed teach that intestinal mucosa function promoters such as omega-3 fatty acids, lactoferrin, prebiotics, etc of pg. 10, lines 21-27 do have a fatty acid profile specially-selected to improve absorption, wherein the fatty acid profile is polyunsaturated; the instant specification does not teach that whey protein or protease specifically claimed in instant claim 55 (from which claims 58-59 depend) as fat transportation aids have the same fatty acid profile or are polyunsaturated. Instead the instant specification only discloses that whey protein or protease is used to promote "the formation of lipoproteins" (pg. 7, lines 1-4; pg. 10, lines 13-21) with no regard to their effect of absorption or specific fatty acid profile. As such the new matter rejection is maintained.

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Applicant further argues that the prior art does not teach an amount of fish oil or anti-inflammatory agent. The Examiner respectfully disagrees as both '933, '237, '718, '226, and '667 all teach amounts of fat/oil including fish oil and as stated above the instant specification teaches that omega-3 fatty acids are anti-inflammatory agents (pg. 7, lines 7-8). '933 specifically teaches 5-40% fat/oil component such as fish oil (col. 5, lines 9-10; col. 2, lines 45), while '237 claims 1-5% fish oil in claim 7 and Examples teach 0.001-60% cod liver oil. Further, '718 teaches fats such as fish oil in an amount no more than 5% (col. 7, lines 35-42), and palatability modifiers such as fish oil in amounts of 0.0001-10% (col. 9, lines 41-53), which overlaps with the instant claimed ranges. '226 has a lipid source such as fish oil in an amount of about 15-35% with the ratio of n-6 to n-3 fatty acids of 5:1 to about 15:1 (pg. 3, lines 39-47), which overlaps with the instant claimed omega-3 fatty acid range. '667 Example 7 teaches 10% fish oil. Thus all the prior art teaches fish oil which contains omega-3 fatty acids in overlapping ranges.

Applicant also argues that '718 does not teach any % of anti-inflammatory agents and only lists a multitude of lactic acid bacteria strains (response pg. 10, last paragraph), the Examiner respectfully points out that the instant specification does not teach that "lactic acid bacteria strains" are "anti-inflammatory agents" (pg. 7, lines 5-8).

### ***Conclusions***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bethany Barham whose telephone number is (571)272-6175. The examiner can normally be reached on M-F, 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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